

## **REMARKS**

This responds to the Office Action dated October 13, 2006 and the Advisory Action dated January 4, 2007.

Claims 1, 11, 35, and 40 are amended. Claims 1-45 are pending in this application.

### **§112 Rejection of the Claims**

Claims 11 and 40 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant has rewritten claims 11 and 40 to overcome the rejection.

### **§102 Rejection of the Claims**

Claims 1, 3, 4, 6, 7 and 12-14 were rejected under 35 U.S.C. § 102(b) as being anticipated by Stokes (U.S. Patent No. 4,506,680).

Applicant has amended claim 1 to better describe the subject matter recited in the claim. Applicant believes claim 1 is not anticipated by the cited reference since the reference does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited reference: a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer and not adjacent to the surface of the electrode including at least one pharmacological agent, as recited in claim 1. In contrast, the reference shows a sheath 24' and a porous coating 34, but does not discuss a first and second layer arranged as recited in claim 1.

Claims 3, 4, 6, 7, and 12-14 include each limitation recited in claim 1 and are therefore also not anticipated by the cited reference. Reconsideration and allowance is respectfully requested.

Claims 16, 18, 35, 36, 41, 42, 44 and 45 were rejected under 35 U.S.C. § 102(b) as being anticipated by Vachon et al. (U.S. Patent No. 5,324,324).

Claims 16 and 18

Applicant traverses the rejection of claim 16. Applicant believes claim 16 is not anticipated by the cited reference since the reference does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited reference: an outer surface of the electrode is coated with two or more layers comprising a first layer including an insulative material and a second layer over the first layer, the second layer including at least one pharmacological agent, as recited in claim 16. In contrast, the reference shows a sheath 38 and a coating material 72, but does not discuss a first and second layer arranged as recited in claim 16. Applicant traverses the characterization of the reference on page 7 of the Office Action where the Office Action asserts that Vachon discloses “a second layer over a first layer (Figs 2-3, 72 over 38 at 58, the neck area)”. In contrast, Vachon does not show or discuss that material 72 is over sheath 38 at any portion of the sheath.

In the Advisory Action dated January 4, 2007, the Examiner states that: “[i]t is apparent that the engaged portion of the tine sheath 38 at the neck area 58 with the conductive electrode 50 that terminates at the electrode distal tip 60 which is thoroughly coated with coating material 72 is covered by the coating material at the junction where they touch because the coating material is on top of the tine sheath as described, shown and interpreted by the Examiner in the Office Action mailed on 13 October 2006, and as restated by the Applicant.” Applicant respectfully traverses this characterization. As argued by Applicant in the prior response, Vachon does not show or discuss that material 72 is over sheath 38 at any portion of the sheath, including the neck area 58. The coating material 72 is not on top of the tine sheath 38, as the Office Action asserts. Accordingly, claim 16 is not anticipated by the cited reference.

Claim 18 includes each limitation recited in claim 16 and is therefore also not anticipated by the cited reference. Reconsideration and allowance is respectfully requested.

Claims 35, 36, 41, 42, 44, and 45

Applicant has amended claim 35 to better describe the subject matter recited in the claim. Applicant believes claim 35 is not anticipated by the cited reference since the reference does not

include each limitation recited in the claim. For instance, Applicant cannot find in the cited reference: coating the first layer of the electrode with a second layer, wherein the second layer comprises a polymer and at least one pharmacological agent, and at least partially coats the first layer, as recited in claim 35. Again, the reference shows a sheath 38 and a coating material 72, but does not discuss a first and second layer arranged as recited in claim 35.

Claims 36, 41, 42, 44, and 45 include each limitation recited in claim 35 and are therefore also not anticipated by the cited reference. Reconsideration and allowance is respectfully requested.

§103 Rejection of the Claims

Claims 30, 33 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) in view of Sirhan et al. (U.S. 2003/0083646).

Applicant traverses the rejection of claims 30, 33, and 34 since there is no suggestion or motivation to combine the references and there is no reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2143. Here, the Examiner has merely asserted that the motivation is "to provide for improved controlled substance delivery to the target tissue site." (Page 9 of Office Action). However, the Stokes reference includes a drug dispenser to deliver drugs. (Abstract). Thus, the reference itself and does not appear to need or suggest improved control substance delivery. Moreover, there is no reasonable expectation of success. The Sirhan reference discusses a stent with drug coatings. Stokes discusses an electrode. There is no evidence that the stent coatings of Sirhan are applicable to the Stokes electrode. This is a hindsight conclusion.

Claims 33 and 34 include each limitation recited in their parent claim and are therefore also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

Claim 2 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) as applied to claim 1 above, and in view of Berthelsen (U.S. Patent No. 4,953,564). Claim 2 includes each limitation of its parent claim and is not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. Reconsideration and allowance is respectfully requested.

Claims 5 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) as applied to claim 1 above, and in view of Vachon et al. (U.S. Patent No. 5,324,324). Claim 5 and 8 include each limitation of their parent claim and are not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. Moreover, even if combined, the combination does not include each limitation recited in the claim. For instance, the combination does not include: a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer and not adjacent to the surface of the electrode including at least one pharmacological agent, as recited in parent claim 1. Reconsideration and allowance is respectfully requested.

Claims 9, 10 and 15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) as applied to claim 1 above, and in view of MacGregor (U.S. Patent No. 4,281,669). Claim 9, 10, and 15 include each limitation of their parent claim and are not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. Reconsideration and allowance is respectfully requested.

Claim 11 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) and MacGregor (U.S. Patent No. 4,281,669) as applied to claim 9 above, and further in view of Vachon et al. (U.S. Patent No. 5,324,324). Claim 11 includes each limitation of its parent claim and is not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. Reconsideration and allowance is respectfully requested.

Claim 17 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. (U.S. Patent No. 5,324,324) as applied to claim 16 above, and further in view of Berthelsen (U.S. Patent No. 4,953,564). Claim 17 includes each limitation of its parent claim and is not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. Reconsideration and allowance is respectfully requested.

Claims 19, 21, 22, 23, 24, 28, 29, 37 and 43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. (U.S. Patent No. 5,324,324) as applied to claims 16, 18, 36 and 42 above, and in view of Stokes (U.S. Patent No. 4,506,680).

**Claims 19, 21, 22, 23, 24, 28, 29**

Claims 19, 21, 22, 23, 24, 28, 29 include each limitation of their parent claim and are not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. For instance, even if combined, the combination does not include: an outer surface of the electrode is coated with two or more layers comprising a first layer including an insulative material and a second layer over the first layer, the second layer including at least one pharmacological agent, as recited in parent claim 16. As discussed above, Stokes shows a sheath 24' and a porous coating 34, but the porous coating is not over the sheath. Likewise, Vachon shows a sheath 38 and a coating material 72, but Vachon does not show or discuss that material 72 is over sheath 38 at any portion of the sheath. Reconsideration and allowance is respectfully requested.

**Claims 37 and 43**

Claims 37 and 43 include each limitation of their respective parent claims and are not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. Reconsideration and allowance is respectfully requested.

Claims 25-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. (U.S. Patent No. 5,324,324) and Stokes (U.S. Patent No. 4,506,680) as applied to claim 21 above, and further in view of MacGregor (U.S. Patent No. 4,281,669). Claim 25-27 include each limitation of their parent claim and are not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above.

Reconsideration and allowance is respectfully requested.

Claim 31 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) and Sirhan et al. (U.S. 2003/0083646) as applied to claim 30 above, and further in view of Berthelsen (U.S. Patent No. 4,953,564). Claim 31 includes each limitation of its parent claim and is not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. Reconsideration and allowance is respectfully requested.

Claim 32 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) and Sirhan et al. (U.S. 2003/0083646) as applied to claim 30 above, and further in view of MacGregor (U.S. Patent No. 4,281,669). Claim 32 includes each limitation of its parent claim and is not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. Reconsideration and allowance is respectfully requested.

Claims 38-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. (U.S. Patent No. 5,324,324) as applied to claim 35 above, and further in view of MacGregor (U.S. Patent No. 4,281,669). Claim 38-40 include each limitation of their parent claim and are not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. Reconsideration and allowance is respectfully requested.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 359-3267 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

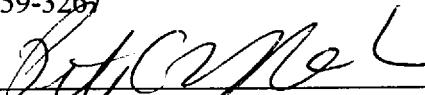
Respectfully submitted,

CHRISTOPHER P. KNAPP ET AL.

By their Representatives,

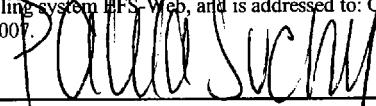
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 359-3267

Date 1/16/07

By 

Peter C. Maki  
Reg. No. 42,832

**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 16 day of January 2007.

Name 

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